

Claims

1. An adjuvant composition comprising (a) polyoxyethylene alkyl ether or ester of general formula (I):
5 $\text{HO}(\text{CH}_2\text{CH}_2\text{O})_n\text{-A-R}$
wherein, n is 1-50, A is a bond or $-\text{C}(\text{O})-$, R is C_{1-50} alkyl or Phenyl C_{1-50} alkyl; and
(b) at least one additional non-ionic surfactant.
2. An adjuvant composition as claimed in claim 1, wherein said additional non-ionic surfactant is an Octoxynol.
- 10 3. An adjuvant composition as claimed in claim 2, wherein said Octoxynol is t-octylphenoxypolyethoxyethanol (TRITON X100™).
4. An adjuvant composition as claimed in any one of claims 1 to 3, additionally comprising one or both of a polyoxyethylene sorbitan ester or cholic acid or derivative thereof.
- 15 5. An adjuvant composition as claimed in any one of claims 1 to 4, characterised in that the polyoxyethylene alkyl ether or ester of formula (I) is haemolytic.
6. An adjuvant composition as claimed in claim 5, characterised in that the degree of haemolytic activity of the polyoxyethylene alkyl ether or ester is in the
20 range of 0.05-0.0001 % as measured in the Guinea Pig blood haemolysis assay.
7. An adjuvant as claimed in claim 5 or claim 6, wherein the polyoxyethylene alkyl ether or ester of formula (I) has a haemolytic activity within a ten fold difference to that of polyoxyethylene-9 lauryl ether or polyoxyethylene-8 stearyl ether, as measured in the Guinea Pig blood haemolysis assay.
- 25 8. An adjuvant composition as claimed in any one of claims 1 to 7, comprising a polyoxyethylene alkyl ether or ester of formula (I), wherein n is 4 to 24.
9. An adjuvant composition as claimed in claim 8, wherein, n is 9.
10. An adjuvant composition as claimed in any one of claims 1 to 7, comprising a polyoxyethylene alkyl ether or ester of formula (I), wherein R is C_{8-20} alkyl or
30 Phenyl C_{8-20} alkyl.
11. An adjuvant composition as claimed in claim 10, wherein R is C_{12} alkyl.

12. An adjuvant composition as claimed in any one of claims 1 to 11, comprising a polyoxyethylene alkyl ether or ester of formula (I), wherein A is a bond, thereby forming an ether.
13. An adjuvant composition as claimed in any one of claims 1 to 12, comprising
5 a polyoxyethylene alkyl ether or ester of formula (I), wherein A is -C(O)-, thereby forming an ester.
14. An adjuvant composition as claimed in any one of claims 1 to 13, wherein the polyoxyethylene ether or ester of formula (I) is selected from the group comprising: polyoxyethylene-9-lauryl ether, polyoxyethylene-9-lauryl ester,
10 polyoxyethylene-9-stearyl ether, polyoxyethylene-8-stearyl ether polyoxyethylene-4-lauryl ether, polyoxyethylene-35-lauryl ether, polyoxyethylene-23-lauryl ether.
15. An adjuvant combination comprising polyoxyethylene-9 lauryl ether and t-octylphenoxypolyethoxyethanol (TRITON X100™).
16. An adjuvant composition as claimed in any one of claims 1 to 15, wherein
15 the total concentration of the detergent present is in the range 0.001-10%.
17. An adjuvant composition as claimed in claim 16, wherein the total concentration of the detergent is in the range 0.001-1%.
18. An adjuvant composition as claimed in claim 17, wherein the total concentration of detergent is in the range of 0.001 to 0.7%.
- 20 19. An adjuvant combination, comprising an adjuvant as claimed in any one of claims 1 to 17, in combination with at least one additional immunostimulant.
20. An adjuvant combination as claimed in claim 19, wherein the at least one additional immunostimulant is selected from the group comprising: LT, CT, 3D-MPL, CpG, and QS21.
- 25 21. An adjuvant composition as claimed in claim 20, wherein the CpG adjuvant is: TCC ATG ACG TTC CTG ACG TT (SEQ ID NO. 1).
22. An adjuvant combination comprising polyoxyethylene-9 lauryl ether, t-octylphenoxypolyethoxyethanol (TRITON X100™), and 3D-MPL.
23. A vaccine comprising an adjuvant as claimed in any one of claims 1 to 22,
30 further comprising an antigen.

24. A vaccine as claimed in claim 23, wherein said antigen is selected from the group comprising: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B, C or E, Respiratory Syncytial virus, human papilloma virus, Influenza virus, Hib, Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Streptococcus, Mycoplasma, Mycobacteria, Haemophilus, Plasmodium or Toxoplasma, stanworth decapeptide; or Tumour associated antigens (TMA), MAGE, BAGE, GAGE, MUC-1, Her-2 neu, LnRH, CEA, PSA, KSA, or PRAME.
25. A vaccine as claimed in claim 24, wherein said antigen in an antigen or antigenic preparation from Influenza virus.
26. A vaccine composition comprising polyoxyethylene-9 lauryl ether, t-octylphenoxypolyethoxyethanol (TRITON X100™) and an influenza virus antigen.
27. A vaccine as claimed in any one of claims 23 to 26, wherein the vaccine is in the form of an aerosol or spray.
28. A vaccine as claimed in any one of claims 23 to 27, for use in medicine.
29. Use of an adjuvant composition as claimed in any one of claims 1 to 22, in the manufacture of a medicament for application onto a mucosal surface or the skin of a patient.
30. Use of a combination of polyoxyethylene-9 lauryl ether and t-octylphenoxypolyethoxyethanol (TRITON X100™) in the manufacture of a vaccine for application onto a mucosal surface of a patient.
31. A spray device, more particularly a bi-dose spray device, filled with a vaccine, as claimed in any one of claims 23 to 27.
32. Use of vaccine composition as defined in any of claims 23 to 27, for the manufacture of a vaccine for the treatment of viral, bacterial, parasitic infections, allergy, or cancer.
33. A method of treating a mammal suffering from or susceptible to a pathogenic infection, or cancer, or allergy, comprising the administration of a safe and effective amount of a vaccine composition according to any of claims 23 to 27 to the mammal.

34. A method of treating a mammal suffering from or susceptible to a pathogenic infection, or cancer, or allergy, comprising the mucosal administration of a safe and effective amount of a vaccine composition according to any of claims 23 to 27.
35. A method of treating a mammal suffering from or susceptible to a pathogenic
5 infection, or cancer, or allergy, comprising the intranasal administration of a safe and effective amount of a vaccine composition according to any of claims 23 to 27.
36. A process for making a vaccine composition according to any one of claims 23 to 27, comprising admixing (a) an adjuvant composition as claimed in any one of
claims 1 to 22, (b) a pharmaceutically acceptable excipient, and (c) an antigen or
10 antigenic composition.